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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,778	08/21/2001	Rodney B. Croteau	WSUR117920	9476
26389	7590	12/10/2004	EXAMINER	
CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC 1420 FIFTH AVENUE SUITE 2800 SEATTLE, WA 98101-2347			LU, FRANK WEI MIN	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/934,778

Applicant(s)

CROTEAU ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 17, 18 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 18 and 43 is/are rejected.
- 7) ☒ Claim(s) 17, 42, and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on February 23, 2004 has been entered.

The claims pending in this application are claims 10, 17, 18, and 42-44. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 10, 18, and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for encoding an isolated, recombinant *Mentha piperita* geranyl diphosphate synthase large subunit protein using a nucleic acid molecule consisting of SEO ID NO:1 and encoding an isolated, recombinant *Mentha piperita* geranyl diphosphate synthase small subunit protein using a nucleic acid molecule consisting of SEO ID NO:10, does not reasonably provide enablement for (1) encoding an isolated, recombinant geranyl diphosphate synthase large subunit protein using any kind of nucleic acid molecule that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEO ID NO:1 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 1 X SSC at 55 °C for 30 minutes and encoding an isolated, recombinant geranyl diphosphate synthase small subunit protein using any kind of nucleic acid molecule that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence

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set forth in SEQ ID NO:10 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 0.5 X SSC at 55 °C for 30 minutes; and (2) performing the same function of SEQ ID NO: 2 using amino acids 1 through 40 of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance in the specification to show that: (1) any kind of nucleic acid molecule that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEQ ID NO:1 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 1 X SSC at 55 °C for 30 minutes can encode an isolated, recombinant geranyl diphosphate synthase large subunit protein and any kind of nucleic acid molecule that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEQ ID NO:10 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 0.5 X SSC at 55 °C for 30 minutes can encode an isolated, recombinant geranyl diphosphate synthase small subunit protein; and (2) amino acids 1 through 40 of SEQ ID

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NO: 2 can perform the same function of SEQ ID NO: 2. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether any kind of nucleic acid molecule recited in claims 10 and 18 can encode an isolated, recombinant geranyl diphosphate synthase large subunit protein and an isolated, recombinant geranyl diphosphate synthase small subunit protein, and whether amino acids 1 through 40 of SEQ ID NO: 2 can perform the same function of SEQ ID NO: 2.

Claims 10 and 18 are directed to an isolated, recombinant geranyl diphosphate synthase large subunit protein from any source and an isolated recombinant geranyl diphosphate synthase protein from any source comprising an isolated, recombinant geranyl diphosphate synthase large subunit protein and an isolated, recombinant geranyl diphosphate synthase small subunit protein and claim 43 is directed to an isolated, recombinant geranyl diphosphate synthase large subunit protein comprising an amino acids 1 through 40 of SEQ ID NO:2. The specification only show that a nucleic acid molecule consisting of SEQ ID NO: 1 can encode an isolated, recombinant *Mentha piperita* geranyl diphosphate synthase large subunit protein (SEQ ID NO: 2) and a nucleic acid molecule consisting of SEQ ID NO: 10 can encode an isolated, recombinant *Mentha piperita* geranyl diphosphate synthase small subunit protein (SEQ ID NO: 11). However, the specification does not provide a guidance to show that any kind of nucleic acid molecule that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEQ ID NO:1 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 1 X SSC at 55 °C for 30 minutes can encode an isolated, recombinant geranyl diphosphate synthase large subunit protein and any kind of nucleic acid molecule that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in

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SEQ ID NO:10 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 0.5 X SSC at 55 °C for 30 minutes can encode an isolated, recombinant geranyl diphosphate synthase small subunit protein, and amino acids 1 through 40 of SEQ ID NO: 2 can perform the same function of SEQ ID NO: 2. In fact, an oligonucleotide from nucleotides 205818 to 205835 of *Bacteroides thetaiotaomicron* VPI-5482 that is 100% identical to nucleotides 1-18 of SEQ ID NO:1 and can hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEQ ID NO:1 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 1 X SSC at 55 °C for 30 minutes can not encode an isolated, recombinant geranyl diphosphate synthase large subunit protein (see attached sequence matches between SEQ ID NO: 1 and nucleotides 205818 to 205835 of *Bacteroides thetaiotaomicron* VPI-5482) and a poly(A) with 20 adenine that is 100% identical to poly(A) tail of 3' of SEQ ID NO:10 and can hybridize to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEQ ID NO:10 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 0.5 X SSC at 55 °C for 30 minutes can not encode an isolated, recombinant geranyl diphosphate synthase large subunit protein. Therefore, it is unclear whether all nucleic acids recited in claims 10 and 18 can encode an isolated, recombinant geranyl diphosphate synthase large subunit protein and an isolated, recombinant geranyl diphosphate synthase small subunit protein.

With these unpredictable factors, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. These undue experimentation at least includes to test whether any nucleic acid recited in claims 10 and 18 can encode an isolated, recombinant

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geranyl diphosphate synthase large subunit protein and an isolated, recombinant geranyl diphosphate synthase small subunit protein and whether amino acids 1 through 40 of SEQ ID NO: 2 can perform the same function of SEQ ID NO: 2.

4. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To the extent that the claimed composition/or methods are not described in the instant disclosure, claim 43 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Although the specification describes that SEQ ID NO: 2 (see sequencing listing), the specification fails to define "a transit peptide" in the specification. Furthermore, in applicant's remarks filed on September 7, 2004, applicant does not indicate which part in the specification supports such claim limitation.

MPEP 2163.06 notes "If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112,

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FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

Response to Arguments

5. Applicant's arguments with respect to claims 10, 11, and 13-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Claims 17, 42, and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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10. No claim is allowed.

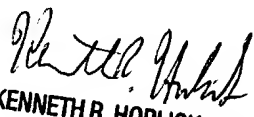
11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (703)872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
December 6, 2004


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER
12/9/04